



K 970258

916-342-4133  
FAX: 916-343-4541

MAY 22 1997

15 January 1997

### 510(k) SUMMARY

The 510(k) summary information required by 21 CFR 807.92 is as follows:

- A. Classification name: Screw, fixation, bone, or appliance, fixation, nail/plate/blade combination, multiple component.

Common/Usual name: Hip screw, hip pin, hip screw and plate, etc.

Proprietary name: Fixano D.S.S. (Double Sliding Screws) System For Osteosynthesis of Unstable Femoral Neck Fractures.

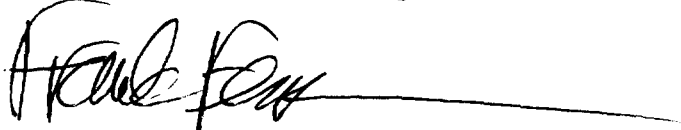
- B. Substantial equivalence: Fixano D.S.S. (Double Sliding Screws) System (K954757), Synthes Dynamic Hip Screw (DHS) (K791619), Howmedica Omega Plus Compression Hip Screw System (K955306), and others.

- C. Device description: The Fixano D.S.S. (Double Sliding Screws) System For Osteosynthesis of Unstable Femoral Neck Fractures is an implantable device to be used in orthopedic trauma procedures.

D. Intended use: The D.S.S. System For Osteosynthesis of Unstable Femoral Neck Fractures is intended for use in the fixation and osteosynthesis of unstable femoral neck fractures.

E. Technological characteristics: The D.S.S. System For Osteosynthesis of Unstable Femoral Neck Fractures is a hip screw mechanism that allows a natural, weight-bearing compression. The D.S.S. screws can be utilized alone, or in combination with a mini-plate, allowing flexibility of osteosynthesis in most configurations of unstable femoral neck fractures.

Submitted,  
**FERGUSON MEDICAL**  
FDA Establishment Registration Number 2937794

A handwritten signature in dark ink, appearing to read 'Frank Ferguson', with a long horizontal line extending to the right.

Frank Ferguson  
Official Correspondent



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAY 22 1997

Mr. Frank Ferguson  
Official Correspondent  
Ferguson Medical  
3407 Bay Avenue  
Chico, California 95973

Re: K970257  
Fixano Double Sliding Screws (D.D.S.)  
with Intramedullary Nail  
**K970258**  
Fixano Double Sliding Screws (D.D.S.) and Mini-Plate  
K970280  
Fixano Double Sliding Screws (D.D.S.) and Sid Plate  
Regulatory Class: II  
Product Codes: HSB, HRS and HRS  
Dated: April 15, 1997  
Received: April 21, 1997

Dear Mr. Ferguson:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined these devices are substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the devices, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your devices in

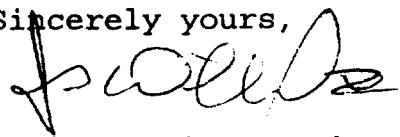
Page 2 - Mr. Frank Ferguson

the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to legally marketed predicate devices results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your devices, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

  
fr Celia M. Witten, Ph.D., M.D.  
Director  
Division of General and  
Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

10(k) Number (If known): K970258

Device Name: Fixano DSS (Double Sliding Screw) System For  
Osteosynthesis of Unstable Femoral Neck  
Fractures

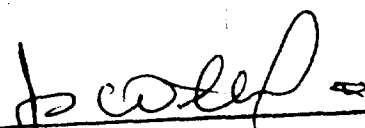
Indications For Use:

This device is indicated for use in the fixation of unstable  
femoral neck fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTEHR PAGE IF NEEDED)

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K970258

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)